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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/246,129	02/08/1999	GUO-LIANG YU	PF141P4	5810

22195 7590 10/21/2002

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EXAMINER	
ROMEO, DAVID S	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 10/21/2002 25

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/246,129	YU ET AL.	
	Examiner	Art Unit	
	David S Romeo	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *42-48,51-56,59,62-66,69,72-77,80,83-89 and 92-94* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *42,46-48,51-56,59,62-66,69,72-77,80,83-89 and 92-94* is/are rejected.

7)☐ Claim(s) *43-45* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The request filed on January 25, 2002 (Paper No. 23) for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09246129 is acceptable and a CPA has been established. An action on the CPA follows.

The amendment filed September 26, 2001 (Paper No. 18) and the preliminary amendment filed January 25, 2002 (Paper No. 24) have been entered. Claims 42-48, 51-56, 59, 62-66, 69, 72-77, 80, 83-89, 92-94 are pending and being examined. Any objection and/or rejection of record that is not maintained and/or repeated in this Office action is withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Citations by the examiner are in an alphanumeric format, such as "(a1)", wherein the "a" refers to the reference cited on the Notice of References Cited, PTO-892, and the "1" refers to the Paper No. to which the Notice of References Cited, PTO-892, is attached.

New formal matters, objections, and/or rejections:

Claim Rejections - 35 USC § 112

Claims 42, 46-48, 51-55, 59, 62-65, 69, 72-74 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification lacks complete deposit information for the deposit of ATCC Deposit No. 75927. While the specification provides enough information for one of skill in the art to

produce a polynucleotide comprising a coding sequence with the same or similar properties as, reproduction of an identical polynucleotide is a highly unpredictable event. Because it does not appear that ATCC Deposit No. 75927 is known and publicly available or can be reproducibly isolated form nature without undue experimentation and because the claims require the use of ATCC Deposit No. 75927, a suitable deposit of the clones is required for patent purposes.

Applicants referral to the deposit of ATCC Deposit No. 75927 at page 4 is insufficient to ensure that all of the conditions of 37 CFR § 1.801-1.809 have been met.

If the deposit was made under the provision of the Budapest Treaty, filing of an affidavit or declaration by applicants or assignees, or a statement by an attorney of record over his or her signature and registration number, stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository, is required. This requirement is necessary when a deposit is made under the provisions of the Budapest Treaty as the treaty leaves these specific matters to the discretion of each State. Amendment of the specification to recite the date of the deposit and the complete name and address of the depository, and amendment of the claims to refer to the accession number, is required. In addition, claims reciting the deposited material must be amended to include the depository accession number of the deposited material.

Furthermore, unless the deposit was made at or before the time of filing, a declaration under 37 CFR 1.132 is necessary to construct a chain of custody. The declaration, executed by a person in a position to know, should identify the deposited clones by its depository accession

number, establish that the deposited clones are the same as that described in the specification and establish that the deposited clone was in applicants' possession at the time of filing.

The new address for the ATCC, effective March 23, 1998, is American Type Culture Collection, 10801 University Boulevard, Manassas, VA 20110-2209.

Claim 56 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claim is directed to a polypeptide which comprises a polynucleotide. The present specification lacks guidance for making, and working examples of, a polypeptide made up of a polynucleotide. It would require undue experimentation for the skilled artisan to make and/or use the full scope of the claimed invention.

Claims 42, 51-54, 55, 56, 59, 62-66, 69, 72-76, 86-89, 92-94 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to polypeptides comprising a fragment of TNF-γ-α, wherein the fragment binds an antibody that binds TNF-γ-α, a polypeptide comprising either 10 or 30 amino acids of TNF-γ-α wherein the polypeptide binds an antibody that binds TNF-γ-α, a polypeptide having at least 90% or 95% sequence identity with TNF-γ-α wherein the polypeptide binds an antibody that binds TNF-γ-α, and a polypeptide encoded by a polynucleotide that hybridizes to

the complement of SEQ ID NO: 1 wherein the polypeptide binds an antibody that binds TNF-γ-α. Various studies indicate that the size of an epitope, the portion of an antigen to which an antibody binds, is approximately equivalent to 5-7 amino acids. See Benjamini (u25), page 40. However, the claims do not require that the polypeptide possess a particular conserved structure or other disclosed distinguishing feature. Thus, the claims are drawn to a genus of polypeptides that is defined only by sequence identity or partial sequence identity.

The specification and claim do not place any limit on the number or type of amino acid substitutions, deletions, insertions and/or additions that may be made to the claimed polypeptide. Thus, the scope of the claim includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in various forms, as indicated above. There is no identification of a particular portion of the structure that must be conserved. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See Fiers v. Revel, 25 USPQ2d 1601 at 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481 at 1483. In Fiddes, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only isolated polypeptides comprising the amino acid sequence set forth in SEQ ID NO: 2, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

The following claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 42, 48, 51-54 are indefinite because they recite the term "mature". Because the instant specification does not identify that material element or combination of elements which is unique to, and, therefore, definitive of "mature" an artisan cannot determine what additional or material functional or structural limitations are placed upon a claim by the presence of this element. The metes and bounds are not clearly set forth.

Claims 42, 51-56, 59, 62-66, 69, 72-77, 80, 83-89, 92-94 are indefinite because they recite either the term "specifically binds" or the term "specific for". Because the instant specification does not identify that material element or combination of elements which is unique to, and, therefore, definitive of "specifically binds" or the term "specific for" an artisan cannot determine what additional or material functional or structural limitations are placed upon a claim by the presence of this element. The metes and bounds are not clearly set forth.

Claims 51, 84, 85 are indefinite because they recite the term "TNF-γ-α". Because the instant specification does not identify that material element or combination of elements which is unique to, and, therefore, definitive of "TNF-γ-α" an artisan cannot determine what additional or material functional or structural limitations are placed upon a claim by the presence of this element. The metes and bounds are not clearly set forth.

Claim 84 is indefinite because it recites the term "TNF-γ-α activity". Because the instant specification does not identify that material element or combination of elements which is unique to, and, therefore, definitive of "TNF-γ-α activity" an artisan cannot determine what additional

or material functional or structural limitations are placed upon a claim by the presence of this element. The metes and bounds are not clearly set forth.

Claim Objections

Claims 51, 85 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. A fragment or polypeptide that binds an antibody specific for TNF-γ-α fails to further limit a fragment or polypeptide, respectively, that specifically binds an antibody that specifically binds the polypeptide of SEQ ID NO: 2.

Specification

The amendment filed September 26, 2001 (Paper No. 18) is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "24" in the paragraph bridging lines 21-36 at page 39. "U034070" in the paragraph bridging lines 20-27 at page 10.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 42, 51, 52, 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Park (n25) in view of Benjamini (u25).

Park discloses a polypeptide comprising a 7 amino acid fragment of the present application's SEQ ID NO: 2, as indicated below:

```
R08329
ID   R08329 standard; protein; 459 AA.
XX
AC   R08329;
XX
DT   04-MAR-1991  (first entry)
XX
DE   Human IL-7 receptor clone 1120.
XX
KW   Interleukin-7 receptor; immune response; pre-B cell growth factor;
KW   Lymphopoietin.
XX
OS   Homo sapiens.
XX
FH   Key             Location/Qualifiers
FT   Peptide         1..20
FT                   /label= Signal peptide
FT   Protein         21..459
FT   Region          240..265
FT                   /label= Transmembrane region
XX
PN   EP403114-A.
XX
PD   19-DEC-1990.
XX
PF   31-MAY-1990;   90EP-0305928.
XX
PR   14-MAR-1990;   90US-0493588.
PR   15-JUN-1989;   89US-0366910.
PR   13-OCT-1989;   89US-0421201.
XX
PA   (IMMU-) IMMUNEX CORP.
XX
PI   Park LS,  Goodwin RG;
XX
DR   WPI; 1990-377843/51.
DR   N-PSDB; Q06901.
XX
PT   Mammalian interleukin-7 receptor DNA, protein and analogues -
PT   used in therapy, diagnosis, assay and antibody production
XX
PS   Claim 4; Fig 2; 28pp; English.
XX
CC   IL-7R gene product may be used in immunoassay or for affinity
CC   purification eg. IL-7R, IL-1 or IL-1R. May also be useful in
CC   regulation of immune response specifically of IL-7 in mammals
CC   esp. humans.
XX
SQ   Sequence   459 AA;

  Query Match             4.0%;  Score 7;  DB 11;  Length 459;
  Best Local Similarity   100.0%;  Pred. No. 28;
  Matches    7;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy      58 TNKFLLI 64
           |||||||
Db      96 tnkflli 102
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See Claim 4; Fig 2. Various studies indicate that the size of an epitope, the portion of an antigen to which an antibody binds, is approximately equivalent to 5-7 amino acids. See

Benjamini (u25), page 40. Accordingly, the IL-7R fragment binds an antibody that binds the corresponding fragment of SEQ ID NO: 2, in the absence of evidence to the contrary, because where the claimed and prior art products are identical or substantially identical in structure or composition, claimed properties or functions are presumed to be inherent, and a prima facie case of either anticipation or obviousness has been established. Applicant has the burden of distinguishing between IL-7R and the claimed peptide. Park also teaches IL-7R comprising a heterologous polypeptide (column 9, lines 15-48), and a composition comprising IL-7R and a pharmaceutical carrier (paragraph bridging columns 17-18).

Conclusion

Claims 43-45 are objected to as being dependent upon a rejected base claim.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 7:30 A.M. TO 4:00 P.M.

IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE FOLLOWING TC 1600 BEFORE AND AFTER FINAL RIGHTFAX NUMBERS:

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CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

David Romeo

DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

DSR
OCTOBER 20, 2002